Proposed Maximum Residue Limit PMRL2017-28

Thiabendazole

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of a new use on soybeans to the product label of Mertect® SC Fungicide, containing technical grade thiabendazole, is acceptable. The specific uses approved in Canada are detailed on the label of Mertect® SC Fungicide, *Pest Control Products Act* Registration Number 13975.

The evaluation of this thiabendazole application indicated that the end-use product has value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRL for thiabendazole is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRL can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

The proposed MRL, to be added to the MRLs already established for thiabendazole, is as follows.

Table 1 Proposed Maximum Residue Limits for Thiabendazole

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Thiabendazole	2-(4-thiazolyl)-1*H*-benzimidazole	0.01	Dry soybeans

[1] ppm = parts per million

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRL proposed for thiabendazole in Canada with corresponding American tolerance and Codex MRL.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food and Feed website, by pesticide or commodity.

Table 2 Comparison of the Canadian MRL, American Tolerance and Codex MRL (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Dry soybeans	0.01	0.02	Not Established

Next Steps

The PMRA invites the public to submit written comments on the proposed MRL for thiabendazole up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRL. Comments received will be addressed in a separate document linked to this PMRL. The established MRL will be legally in effect as of the date that it is entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limit

Residue data for thiabendazole in soybeans were submitted to support the domestic use of Mertect® SC Fungicide on soybean seeds. In addition, a processing study in treated soybean seeds was reviewed to determine the potential for concentration of residues of thiabendazole into processed commodities.

Maximum Residue Limit

The recommendation for maximum residue limit (MRL) for thiabendazole was based upon the submitted field trial data. Table A1 summarizes the residue data used to calculate the proposed MRL for soybean.

Table A1 Summary of Field Trial and Processing Data Used to Support MRL

Commodity	Application Method/ Total Application Rate (g a.i./ 100 kg of seed)[1]	Days After Planting (days)	Lowest Average Field Trial Residues (ppm)	Highest Average Field Trial Residues (ppm)	Experimental Processing Factor
Soybean	Seed treatment/ 40	46-153	<0.01	<0.01	No quantifiable residues were observed at exaggerated rates

[1] g a.i./100 kg of seed = grams of active ingredient per 100 kilograms of seed.

As there is no expectation of quantifiable residues in animal matrices, MRLs will not be recommended for eggs, meat, milk, fat, and meat by-products of cattle, goats, hogs, horses, poultry and sheep in the context of the current petition.

Following the review of all available data, an MRL as proposed in Table 1 is recommended to cover residues of thiabendazole. Residues of thiabendazole in soybeans at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.